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INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Article 36 and Rule 70)

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Applicant's or agent's file reference P14241PCDK/LN/ar	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)	
International application No. PCT/DK2004/000068	International filing date (day/month/year) 03.02.2004	Priority date (day/month/year) 03.02.2003
International Patent Classification (IPC) or both national classification and IPC A61F5/24		
Applicant TYTEX A/S et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets, including this cover sheet.
 - ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 8 sheets.

3. This report contains indications relating to the following items:
 - I ☒ Basis of the opinion
 - II ☐ Priority
 - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - IV ☐ Lack of unity of invention
 - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - VI ☐ Certain documents cited
 - VII ☐ Certain defects in the international application
 - VIII ☐ Certain observations on the international application

Date of submission of the demand 03.09.2004	Date of completion of this report 29.10.2004
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Schmierer, U Telephone No. +49 89 2399-2603 

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/DK2004/000068

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*):

Description, Pages

2, 5-13 as published
1, 1A, 3, 3A, 4 received on 06.09.2004 with letter of 03.09.2004

Claims, Numbers

1-13 received on 06.09.2004 with letter of 03.09.2004

Drawings, Sheets

1/3-3/3 as published

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. **PCT/DK2004/000068**

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-13
	No: Claims	
Inventive step (IS)	Yes: Claims	1-13
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-13
	No: Claims	

2. Citations and explanations

see separate sheet

Re Item V**Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

- (1) Reference is made to the following document/s/:
- D1: US-A-6 080 125A
D2: US-A-3 783 879A
D3: US-A-3 454 003A
- (2) The problem is to provide a clothing article as a mass article suited for persons with (ostomy) hernia, which article fits even at small variations in body size and shape and which article provides for correct compression.
- (3) The document D1 is regarded as being the closest prior art to the subject-matter of both, method claim 1 and independent apparatus claim 9 and shows an abdominal postoperative binder which is made from inelastic material (such as Neoprene (TM)) to exert mechanical compression on a patient. The binder is cut out from a rectangular sheet.
- (4) The subject-matter of both, claims 1 and independent apparatus claim 9 differs from this known binder in that the clothing article is a knitted seamless tubular item with an anatomic fit for establishing a firm yet elastic structure for producing compression of between 15 to 50 mm Hg, and which provides an approximately constant compression within a certain range of user's size and shapes. Thus, claims 1 and 9 are new (Article 33(2) PCT). Said claims further are inventive (Article 33(3) PCT), since from the inelastic material the use of elastic material can not be derived in an obvious way. Further, knitting of a tubular item can not be derived from a rectangular sheet.
- (4.1) Claims 2 to 8 and 10 to 13 are dependent on either claim 1 or independent apparatus claim 9 and as such also meet the requirements of the PCT with respect to novelty and inventive step.
- (5) D2 refer to a hip girdle made of elastic material. Neither the claimed elastic compression nor the tubular seamless item is mentioned there and thus not made obvious.
- (5.1) Undergarment combined with straps.

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MANUFACTURE OF A GARMENT

Background of the invention

5 The present invention concerns a method for manufacturing a clothing article for use with persons that have developed a hernia or are in danger of developing a hernia, preferably an ostomy hernia, which clothing article is made for exerting compression on the user and intended for being disposed around the lower part of the body of the user and made with a predefined size and shape. The invention furthermore concerns such a clothing article.

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By hernia, as used in the present patent application, is understood an abnormal protrusion of an organ or parts thereof through the wall of a body cavity. With hernia is furthermore understood a bulging appearing around a site of operation, e.g. after an ostomy operation.

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For persons suffering from hernia, it is important to use a bandage or clothing article that exerts compression against the skin in order that the hernia is kept in place inside. Such a bandage or clothing article may also be used as a preventive measure.

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In particular for persons that have gone through an ostomy operation, and who subsequently have acquired an ostomy hernia, it is important to get a bandage or clothing article which exert compression in an area around the ostomy aperture. Furthermore, it is important that the ostomy aperture fits exactly to the type of ostomy bag used by each individual person, and which at the same time is correctly disposed in the clothing article. If the aperture in the clothing article is too narrow, it can be difficult to mount the ostomy bag, and if the aperture is too large, there will be a risk that the hernia or a part thereof is pressed out through the aperture.

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A number of clothing articles are known where the required compression is produced by different belts and straps which are tightened by being taken on, or after the user has put the clothing article on. By having elastic bands extending in circumferential direction, desired compression can be established after the user having put on the

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clothing article. However, such products will be unsuitable for use with ostomy hernia,

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clothing article which does not have the drawbacks of the prior art products, which is flexible in making and adaptation, and which therefore is suited for mass production. It is thus desirable to be able to produce clothing articles in a predefined variation of size and shape which has anatomical adaptation to users with different size. Furthermore it is desirable to make a comfortable clothing article that establishes the required compression for the daily use of the person, and which additionally can be used as "measuring panty brief" for use in determining the centre of an ostomy when speaking of an ostomy hernia or other operation hernia.

10 The object of the present invention is to provide a clothing article, preferably in the form of a panty brief which is suited for mass production and which nevertheless is easy to put on, and which simultaneously is suited for persons that have developed a hernia or are in danger of developing a hernia, preferably an ostomy hernia, as there is provided a size and a shape providing a fit which even at small variations in body size and shape ensure correct compression and possibility of a correct and secure positioning of an ostomy aperture in the clothing article.

20 According to the invention, this is achieved with a method of the kind mentioned in the introduction, which is peculiar in knitting a seamless tubular item, which is made with anatomic fit for establishing a firm yet elastic structure for producing compression of between 15 to 50 mmHg within a previously selected area of the clothing article, and which provides an approximately constant compression within a certain range of users' sizes and shapes.

25 In a particular embodiment, the method includes a step for extending the material in the tubular item for establishing the firm yet elastic structure in a clothing article with desired fit.

30 In a particular embodiment, the method according to the invention may be peculiar by a step placing the tubular item on a form with a predefined size and shape for selective fixation of the item while located on the form.

The clothing article according to the invention is peculiar in that it is formed by a

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seamless, knitted, tubular item which is intended for being disposed around the lower

body part of the user, and which is made with a firm yet elastic structure for forming a compression between 15 and 50 mmHg within a pre-selected area of the clothing article in order to provide an anatomical fit, and which provides an approximately constant compression within a certain range of users' sizes and shapes.

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The clothing article is preferably extended or fixed in order to be made with anatomical fit in the predefined size and shape. Furthermore, the clothing article is preferably peculiar in that the tubular item is sewn together at one end for forming a panty brief with a lower body part, groin area and leg openings.

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By the invention there is thus created a clothing article that has an anatomical adaptation in size and shape with a variation which is selected in advance. It may be said that a clothing article is formed which in non-extended or 'slack' condition has a greater size, making it easier for the user to put on the clothing article, even if it has a compression which is necessary for supporting a hernia. The formed compressive area will preferably be formed on the front side of the clothing article.

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According to the invention, it is thus possible to form a compressive area which can be used to prevent and/or secure a hernia, e.g. in connection with ostomy. The compression is created by knitting a high percentage of elastic yarns, e.g. elasthane, possibly in combination with a compact knitting structure and a firm, tight stitch pattern. Due to extension, the clothing article will become easier to put on since it is formed with a size which is 'greater' than a clothing article with corresponding properties for compression. Possibly, the clothing article is formed particularly larger in areas for buttocks and hips.

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If the clothing article is to be used in connection with ostomy, the compression area is to have such nature that an aperture can be made on the relevant place without the material breaking, e.g. because of laddering. This is established by a suitable choice of knitting structure, edge covering, heat fixation or other sealing, e.g. by silicone or PU-film. With such techniques it is possible to avoid that the clothing article breaks when forming an ostomy aperture. Possibly the aperture is laced to ensure that the hernia is not partially penetrating out of the aperture.

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CLAIMS

1. Method for manufacturing a clothing article for use with persons that have developed a hernia or are in danger of developing a hernia, preferably an ostomy hernia, which clothing article is made for exerting compression on the user and intended for being disposed around the lower part of the body of the user and made with a predefined size and shape, characterized by knitting a seamless tubular item, which is made with anatomic fit for establishing a firm yet elastic structure for producing compression of between 15 to 50 mmHg within a previously selected area of the clothing article, and which provides an approximately constant compression within a certain range of users' sizes and shapes.
2. Method according to claim 1, characterized by a step for extending the material in the item or for selective fixation of the item while it is placed on a form with a predefined size and shape.
3. Method according to claims 1 or 2, characterized by a step for sewing together the tubular item for forming a panty brief with a lower body part area, groin area and leg openings.
4. Method according to claim 3, characterized in that the step for sewing together the tubular item for forming a panty brief with lower body part area, groin area and leg openings is performed optionally before or after the fixation step on the form.
5. Method according to claim 3 or 4, characterized in that in the groin area in the panty brief there is provided an aperture so that the user can relieve himself without taking off the panty brief.
6. Method according to any preceding claim, characterized in that the clothing article is made by circular knitting on a body size machine or a rectilinear knitting machine with two needle bars, the machines preferably being electronic controlled.
7. Method according to any preceding claim, characterized in that the extension or

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fixation is performed with varying intensity across the clothing article for establishing

varied extension or elasticity and firmness in the article and thereby also varied compression when the clothing article is placed on a user.

- 5 8. Method according to any preceding claim, **characterized in that** elastic yarns, preferably elasthane, are used in a part between 15 and 60%, preferably between 30 and 50%, of the areas of the clothing article, which are to exert compression on the user's body.
- 10 9. Clothing article formed with a predefined size and shape for use with persons that have developed a **hernia or are in danger of developing a hernia, preferably an ostomy hernia, characterized in that** it is formed by a seamless, knitted, tubular item which is intended for being disposed around the lower body part of the user, and which is made with a firm yet elastic structure for forming a compression between 15 and 50 mmHg within a pre-selected area of the clothing article in order to provide an anatomical fit, and which provides an approximately constant compression within a certain range of users' sizes and shapes.
- 15 10. Clothing article according to claim 9, **characterized in that** the tubular item is preferably extended or fixed in order to provide the anatomical fit.
- 20 11. Clothing article according to claim 9 or 10, **characterized in that** the tubular item is sewn together at one end for forming a panty brief with lower body part, groin area and leg openings.
- 25 12. Clothing article according to claim 9, 10 or 11, **characterized in that** it includes elastic yarns, preferably elasthane, in a part of between 15 and 60%, preferably between 30 and 50%, in the areas which in use are to exert compression on the user's body.
- 30 13. Clothing article according to claim 9 or 10, **characterized in that** in circumferential direction it has a material that display a force/elongation curve including a largely flat curve pattern.